

Applicants: Howard J. Worman and Naoto Mamiya
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REMARKS

Claims 79-100 were pending in the subject application. By this Amendment, Applicants have canceled claims 79-100 and added new claims 101-106. Accordingly, claims 101-106 are currently pending.

Claims 101-106 correspond to previously pending claims 44-49. Consequently, the new claims are supported by the application as filed.

Objection to Non-Responsive Amendment

In the September 23, 2003 Communication, the Examiner objected to claims 79-100 as allegedly being drawn to a non-elected invention because they are directed to a method of inhibiting the attachment of hepatitis C virus onto a cell or of preventing the infection of a cell by a hepatitis C virus, which comprises contacting the cell with an effective amount of a compound which inhibits the binding of hepatitis C virus envelope E2 protein to a cellular protein associated with hepatitis C virus attachment onto cells identified by the recited steps, with virtually nothing known about the structural or chemical features of the compound. The Examiner alleged that these claims are not directed to the same subject matter that was previously recited in claims 44-49 which were drawn to a method of inhibiting attachment of hepatitis C virus into a cell, which comprises contacting the cell with an effective amount of E₀ protein having amino acids 1-120 of SEQ ID NO:1 to the subject, wherein the E₀

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protein is capable of inhibiting the attachment of hepatitis C virus onto the cell by specifically binding to the hepatitis C virus envelope E2 protein. The Examiner alleged that in the previously examined subject matter, the E₀ protein is responsible for the inhibition of the attachment of hepatitis C virus onto a cell, whereas the newly added claims require a compound of unknown structural features having the ability to inhibit the binding of hepatitis C virus envelope E2 protein to a cellular protein associated with hepatitis C virus attachment onto cells (including the E₀ protein) to inhibit attachment of hepatitis C virus onto a cell. The Examiner therefore alleged that the subject matters are drawn to different methods requiring different starting materials, and therefore they also require different technical considerations for attaining the desired end-results. Accordingly, the Examiner stated that claims 79-100 are not under consideration because (a) they are directed to a non-elected invention, (b) it is improper to change invention in RCE which is not a new filing (37 CFR 1.145). The Examiner stated that Applicants must submit claims directed to the elected invention.

In response, Applicants have canceled claims 79-100 and added new claims 101-106. New claims 101-106 correspond to previously pending claims 44-49 and claim the same subject matter. Accordingly, the Examiner's objection is now moot.

With regard to the lack of enablement rejection of previously pending claims 44-49 raised by the Examiner in the December

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23, 2003 Final Office Action, Applicants maintain that the claims are enabled by the specification. Applicants note that the Examiner's alleged that the binding of the Eo protein having SEQ ID NO:1 and the Eo1 protein with a portion of the hepatitis C virus E2 envelope protein observed via the yeast two hybrid assay, which was described in the specification, does not enable claims to treatment or prevention of hepatitis C or delaying the progress of liver disease in a subject. The Examiner cited Rosa et al. as teaching that in contrast with the E2 protein expressed in mammalian cells, E2 protein expressed in yeast or insect cells are not capable of binding to human cells, and the Examiner therefore alleged that it is unclear what significance the interaction between Eo or Eo1 protein with a portion of a hepatitis C virus E2 envelope protein solely in yeasts has for therapeutic effects on a human subject. The Examiner further cited Luban et al. as illustrating the problems and unreliability of the two-hybrid screen assays.

In response, Applicants maintain that the art cited by the Examiner does not establish the status in the art with respect to two-hybrid yeast assays as indicative of the binding of a protein to an E2 protein expressed in mammalian cells. In support of their contention, Applicants draw the Examiner's attention to Boner, W. and Morgan, I.M. "Novel cellular interacting partners of the human papillomavirus 16 transcription/replication factor E2" Virus Res. (2002) 90(1-2):113-8, the abstract of which is attached hereto as **Exhibit A**. As indicated in the abstract, the authors "carried out a

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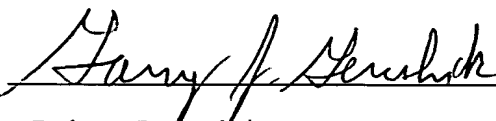
yeast two-hybrid screen with the amino-terminus of E2..." in order to identify the cellular interacting partners for HPV16 E2, a human virus. Applicants further note that the authors performed their screen with a portion of the E2 protein and not the whole protein. Accordingly, Applicants contend that the use of a yeast two-hybrid screen with a portion of the E2 protein to determine the binding to a human E2 protein in a reference as recent as 2002 indicates that the concerns raised by Rosa et al. and Luban et al. do not accurately reflect the state of the art. Consequently, Applicants contend that new claims 101-106 are enabled by the subject specification and respectfully request that the Examiner reconsider and withdraw this rejection.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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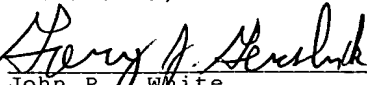
No fee is deemed necessary in connection with this Amendment.
However, if any additional fee is required, authorization is
hereby given to charge the amount of such fee to Deposit
Account No. 03-3125.

Respectfully submitted,



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